



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS Proost, et al.

**EXAMINER:** 

Roark, Jessica H.

U.S.S.N.:

09/537,858

**GROUP:** 

1644

FILED:

March 28, 2000

Conf. No.

5522

FOR:

**AMINO-TERMINALLY TRUNCATED RANTES AS CHEMOKINE** 

**ANTAGONISTS** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## **CERTIFICATE OF MAILING**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 30, 2003.

By: \_ lig

Crystal Slason

## AMENDMENT TRANSMITTAL

- 1. Transmitted herewith is an Amendment and Response to the Non-Final Office Action mailed on March 31, 2003; and
- Copy Transmittal of Formal Drawings, including 9 Sheets of Formal Drawings Figs. 1-7, 8A, 8B, 9 and 10), Copy of Office Action mailed on March 31, 2003, and A Copy of Draftperson's Patent Drawing Review.

U.S. Application No.: 09/537,858

## **STATUS**

[	]	а	small	entity.
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## **EXTENSION OF TERM**

NOTE: "Extension of Time in Patent Cases (Supplement Amendments) — If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.

If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of December 10, 1985 (1061 O.G. 34-35).

NOTE: See 37 C.F.R. § 1.645 for extensions of time in interference proceedings, and 37 C.F.R. § 1.550(c) for extensions of time in reexamination proceedings.

3. The proceedings herein are for a patent application and the provisions of 37 C.F.R. § 1.136 apply.

(complete (a) or (b), as applicable)

(a) [X] Applicant petitions for an extension of time under 37 C.F.R. § 1.136 (fees: 37 C.F.R. § 1.17(a)(1)-(4)) for the total number of months checked below:

	Extension	Fee for other than	Fee for
	(months)	small entity	small entity
[]	one month	\$ 110.00	\$ 55.00
ĪĪ	two months	\$ 410.00	\$205.00
[X]	three months	\$ 930.00	\$465.00
ĪĪ	four months	\$1,450.00	\$725.00

Fee: \$ 930.00

If an additional extension of time is required, please consider this a petition therefor.

U.S. Application No.: 09/537,858

## (check and complete the next item, if applicable)

[]	An extension for months has already therefor of \$ is deducted from the total extension now requested.	been secured. The fee paid
	Extension fee due with this request	\$ <u>930.00</u>
	OR	

(b) [] Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition for extension of time.

## **FEE FOR CLAIMS**

4. The fee for claims (37 C.F.R. § 1.16(b)-(d)) has been calculated as shown below:

[Col. 1] Small Entity [Col. 2]

[Col. 3] Small Entity

Other Than a

Claims Remaining After Amendment	Highest No. Previously Paid For	Present Extra	Rate	•	Additional Fee	R	ate		ditional Fee
Total	Minus	=	x \$ =	9	\$	x =	\$18	\$.	00
Indep.	Minus	=	x \$4 =	2	\$	X =	\$84	\$.	00
[ ] First Presentation of Multiple Dependent Claim			+\$140	) =	:	+\$	280 =	=\$	
			Total \$0.00	Α	ddit. Fee:	To:		ldit.	Fee \$

(Am ndment Transmittal—page 3 of 5)

Attorney Docket No.: 49674 CPA (72024) U.S. Application No.: 09/537,858

- \* If the entry in Col. 1 is less than the entry in Col. 2, write "O" in Col. 3,
- \*\* If the "Highest No. Previously Paid For" IN THIS SPACE is less than 20, enter "20".
- \*\*\* If the "Highest No. Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest No. Previously Paid For" (Total or Indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

WARNING: "After final rejection or action (§ 1.113) amendments may be made canceling claims or complying with any requirement of form which has been made." 37 C.F.R. § 1.116(a) (emphasis added).

(complete (c) or (d), as applicable)

(c) [X] No additional fee for claims is required.

OR

(d) [ ] Total additional fee for claims required

## **FEE PAYMENT**

5. [X] Attached is a check in the sum of \$930.00. Charge Account No. 04-1105 the sum of \$

## **FEE DEFICIENCY**

NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO Finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, (1065 O.G. 31-33).

U.S. Application No.: 09/537,858

6. **[X]** If any additional extension and/or fee is required, charge Account No. <u>04-1105</u>.

Respectfully submitted,

Date: September 30, 2003

3v:

Dianne M. Rees, Ph.D. Registration No. 45,281 EDWARDS & ANGELL, LLP Intellectual Property Group

PO Box 9169 Boston, MA 02209

Telephone: 617-439-4444

Fax: 617-439-4170

Customer No: 21,874

BOS2\_349864.1



## N THE UNITED STATES PATENT AND TRADEMARK OFFICE

**APPLICANTS** 

Proost, et al.

**EXAMINER:** 

Roark,

Jessica H.

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**GROUP:** 

1644

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FOR:

AMINO-TERMINALLY TRUNCATED RANTES AS

CHEMOKINE ANTAGONISTS

Mail Stop: Official Draftsperson Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

## TRANSMITTAL OF FORMAL DRAWINGS

In response to the OFFICIAL ACTION mailed on <u>March 31 2003</u>, attached please find:

(a) the formal drawing(s) for this application.

#### **CERTIFICATE OF MAILING (37 C.F.R. SECTION 1.8(a))**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the united States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Crystal Slason

(type or print name of person mailing paper)

Date: September 30, 2003

Signature of person mailing paper

WARNING:

"Facsimile transmissions are not permitted and if submitted will not be accorded a date of receipt" for "(4) Drawings submitted under sections 1.81, 1.83 through 1.85, 1.152, 1.165, 1.174, 1.437...." 37 C.F.R. section

1.6(d)(4).

Number of Sheets: 9, Figures 1-7, 8A, 8B, 9 and 10.

NOTE: "Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawings a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page. In addition, a reference to the application number, or, if an application number has not been assigned, the inventor's name, may be included in the left-hand comer, provided that the reference appears within 1.5 cm (9/16 inch) from the top of the sheet" (37 C. F. R. Section 1.84(c)).

- [X] Each sheet of drawing indicates the identifying indicia suggested in section 1.84(c) on the reverse side of the drawing.
- (b) a copy of the NOTICE OF PATENT DRAFTSPERSON'S DRAWING REVIEW
- (c) a copy of the OFFICIAL ACTION mailed March 31 2003.

Respectfully submitted,

Date: September 30, 2003

Bv:

Dianne M. Rees, Ph.D.

Diame Co.

Reg. No. 45,281

**EDWARDS & ANGELL, LLP** 

PO BOX 9169

Boston, Massachusetts 02209

Tel: 617-951-4444 Fax: 617-439-4170 Customer No: 21,874

BOS2\_349867.1



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Rv

Cevstal Slason

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

## Sir/Madam:

This communication is in response to the Non-Final Office Action Mailed March 31, 2003.

## **RESPONSE**

## **Pending claims**

Claims 24-30 are pending. Applicants request clarification as to the Examiner's remarks regarding claim renumbering. The Examiner states that misnumbered newly added claims 26-32

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Amendment and Response to Office Action

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have been renumbered 24-30. The claims provided with Applicants' CPA filing are numbered

24 to 30 and thus renumbering should not have been required. In view of the Examiner's

comments in connection with the rejection made under 35 U.S.C. § 112, second paragraph, it

appears that the Examiner may have referred to a previous set of claims in preparing the Office

Action.

**Drawings** 

The Examiner has requested a new set of formal drawings with identifying information

placed on the front of each sheet and centered within the top margin. Applicants have complied

with the requirement and submit herewith as a separate paper with a transmittal letter addressed

to the Official Draftsperson, a new set of formal drawings.

**Sequence Compliance** 

The Office Action indicates that the CRF filed on January 22, 2003 has been found

acceptable and entered.

Rejection of Claims 24-30 Under 35 U.S.C. § 112, Second Paragraph

Claims 24 –30 are rejected under 35 U.S.C. § 112 as being indefinite. The Examiner

states that the claims "reference an amino acid sequence with 68 amino acids (e.g., claim 1

recites 'residues 2-68 of a RANTES polypeptide according to SEQ ID NO:2') however, SEQ ID

NO:2 is only 66 amino acids in length." The Examiner states that for examination purposes

"SEQ ID NO: 2 will be interpreted as referring to a mature RANTES polypeptide as set forth in

Figure 1..."

Applicants traverse the rejection as it misstates the language of the claims filed with

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Amendment and Response to Office Action

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Applicants' CPA filing of January 21, 2003 Claim 24 (corresponding to the first pending claim), recites as follows:

An isolated amino-terminally truncated RANTES polypeptide comprising residues 2-68 of a RANTES polypeptide according to SEQ ID NO: 1, wherein the truncated RANTES polypeptide lacks NH<sub>2</sub>-terminal amino acid residue 1 and has chemokine antagonistic activity.

Therefore, there is no ambiguity in the claims since SEQ ID NO. 1 is 68 amino acids. Applicants respectfully submit there is no need to submit a new sequence listing. Accordingly, Applicants respectfully submit that the rejection is improper and should be reconsidered and withdrawn.

## Rejection of Claims 25 and 28 Under 35 U.S.C. § 102(a)

Claims 25 and 28 are rejected under 35 U.S.C. § 102(a) as being anticipated by Noso, et al., J. Immunol. 156: 1946-1953, 1996 ("Noso"). The Examiner asserts that Noso teaches an amino-terminally truncated RANTES consisting of 66 amino acids and derived from dermal fibroblasts. The Examiner asserts that the amino acid sequence of SEQ ID NO: 3 would be an inherent property of the RANTES taught by Noso since Figure 3 of Noso indicates that amino acids 1 and 2 are missing from the protein. The Examiner asserts that an isolated form is taught at page 1950.

Applicants respectfully traverse the rejection. In applying the rejection, the Examiner is improperly ignoring limitations of the claims that require that the polypeptide be both isolated and have chemokine antagonistic activity. Noso is unable to demonstrate chemokine antagonistic activity in the fraction collected which comprises RANTES amino acids 3-68 *along* 

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Amendment and Response to Office Action

Page 4 of 6

with other impurities which leads Noso to state that "the loss of the two N-terminal residues, serine and proline, does not affect Eo-chemotactic activity of RANTES" (emphasis added). Since Noso is unable to demonstrate a fraction that comprises the claimed activity, Noso's fraction necessarily does not comprise an isolated form of the polypeptide. Accordingly, Applicants respectfully submit that the rejection is improper and should be reconsidered and withdrawn.

## Rejection of Claims 24 and 29 Under 35 U.S.C. § 102(e)

Claims 24 and 29 are rejected under 35 U.S.C. § 102 (e) as being anticipated by U.S. Patent No. 6,168,784 by Offord, et al. ("Offord"). The Examiner asserts that SEQ ID NO: 2 of Offord is a mature RANTES polypeptide of 67 amino acids lacking the Ser found at position 1 of the mature polypeptide. The Examiner further asserts that the polypeptide has chemokine antagonistic activities. Applicants respectfully traverse the rejection. Offord discloses N-terminally modified RANTES derivatives that have chemokine antagonistic activity. Offord does not disclose that an isolated polypeptide, i.e., not chemically modified, possesses such activity. Accordingly, the reference does not disclose all of the elements of the claims as required for anticipation under section § 102.

## Rejection of Claims 13-23 Under 35 U.S.C. § 103(a)

Claims 24-30 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gong, et al., J. Biol. Chem. 271: 1051-10, 1996 ("Gong"). The Examiner asserts that Gong teach amino terminally truncated RANTES lacking N-terminal amino acids corresponding to amino acid residues 1, 1-2, 1-3, or 1-4, and having chemokine antagonistic activity. The Examiner asserts that this rejection is applicable as the claims are not limited to amino terminally truncated

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Amendment and Response to Office Action

Page 5 of 6

proteins which are deleted only for residues 1, 1-2, 1-3, or 1-4. Applicants traverse the rejection.

The claims are additionally rejected over U.S. Patent No. 5,739,103 ("Rollins") in view of Proudfoot, et al. (J. of Biol. Chem. 1996, 271: 2599-2603) ("Proudfoot"). The Examiner cites Proudfoot as teaching recombinant expression of RANTES and the importance of the N-terminus of RANTES to receptor binding and cellular activation. The Examiner acknowledges that neither Rollins nor Proudfoot teach the specific truncations claimed. However, the Examiner asserts that the motivation to produce additional truncations is the motivation to optimize and screen the small genus of truncations taught by Rollins.

It is the Examiner's position that despite Gong's teachings of the variable effects of truncations it would be obvious to try to obtain additional truncations. The Examiner asserts that there would be motivation to evaluate the effect of such compounds with the expectation of inhibiting at least some models of inflammation. The Examiner provides not support for any belief that such truncations would inhibit any models of inflammation in view of Gong's teachings that RANTES polypeptides consisting of residues 6-68, i.e., the smallest truncation shown by Gong, showed the *least* displacement and therefore the *least* amount of inhibition in the assays used to evaluate efficacy. Further, the Examiner points to no teaching in either Rollins or Proudfoot that would motivate one of skill in the art to generate the specific truncations claimed with the expectation of obtaining truncations with chemokine antagonistic activity.

Therefore, contrary to the Examiner's assertion, one of skill in the art would *not* be motivated to make truncations with fewer than six amino acids to obtain an effective chemokine inhibitor. Additionally, "obvious-to-try" is an incorrect standard where the claimed result, the generation of compounds and pharmaceutical compositions *with chemokine antagonistic activity*, is not at all predictable. See, *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990).

U.S.S.N.: 09/537,858 Filed: February 22, 2002

Amendment and Response to Office Action

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## **CONCLUSION**

Applicants submit that the claims are allowable and that the Application is now in condition for allowance. Applicants respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite

prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

Date: September 30, 2003

Dianne Rees, Ph.D. (Reg. No. 45,281)

**EDWARDS & ANGELL, LLP** 

PO BOX 9169

Boston, Massachusetts 02209

(617) 951-4444

Customer No: 21,874

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	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
TPE	09/537.858 03/28/2000		Paul Proost	49674	5522	
0	21874	7590 03/31/2003				
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à.	EDWARDS P.O. BOX 91 BOSTON, M	69 A 02209	RECEIVED	ROARK, JE	ESSICA H	
TRADEM	ARTI			ART UNIT	PAPER NUMBER	
			ARR LO PPP3	1644		
			EDWARDS ANDELL IP DKE BRONSTEIN ROBERT O CUSHMAN	DATE MAILED: 03/31/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

Edwards & Angoli LLD

Dike, Bronstein, Proberts & Cushman

HOUSE DUE

101 Federal St. Egston, MA-931

Date Recid\_\_\_\_

Docketed For 6

Approved..\_\_\_\_

COPY

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OCT 0 2 2003 N	Application No.	Applicant(s)
\2	09/537,858	PROOST ET AL.
Offic Action Summany ADEMIN	Examiner	Art Unit
	Jessica H. Roark	1644
The MAILING DATE of this communication ap		
Period f r Reply		
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.  after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a rep  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statut  - Any reply received by the Office later than three months after the mailin  earmed patent term adjustment. See 37 CFR 1.704(b).  Status	136(a). In no event, however, may a reply be ly within the statutory minimum of thirty (30) d will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDON	timely filed lays will be considered timely. In the mailing date of this communication. INED (35 U.S.C. § 133).
1) Responsive to communication(s) filed on 21.	January 2003 .	
<u> </u>	nis action is non-final.	
3) Since this application is in condition for allow closed in accordance with the practice under		
Disp sition of Claims	i- 4bli4i	
4) Claim(s) 24-30 (as renumbered) is/are pendir		
4a) Of the above claim(s) is/are withdra	iwn from consideration.	
5) Claim(s) is/are allowed.		
6) Claim(s) <u>24-30</u> is/are rejected.		
7) Claim(s) is/are objected to.	or election requirement	
8) Claim(s) are subject to restriction and/o	or election requirement.	
9) The specification is objected to by the Examine	er.	
10)⊠ The drawing(s) filed on 28 March 2000 is/are:		by the Examiner.
Applicant may not request that any objection to the		
11) The proposed drawing correction filed on	- · · · · · · · · · · · · · · · · · · ·	
If approved, corrected drawings are required in re	eply to this Office action.	
12) The oath or declaration is objected to by the Ex	xaminer.	
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreig	n priority under 35 U.S.C. § 119	(a)-(d) or (f).
a)⊠ All b)□ Some * c)□ None of:		
1. Certified copies of the priority document	ts have been received.	
2. Certified copies of the priority document	ts have been received in Applica	ation No
<ul> <li>3. Copies of the certified copies of the price application from the International But See the attached detailed Office action for a list</li> </ul>	ureau (PCT Rule 17.2(a)).	-
14) Acknowledgment is made of a claim for domest	tic priority under 35 U.S.C. § 119	e)(e) (to a provisional application).
a) ☐ The translation of the foreign language pro		
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) Notice of Informa	ary (PTO-413) Paper No(s)  Il Patent Application (PTO-152)
S. Patent and Trademark Office		

Art Unit: 1644

#### RESPONSE TO APPLICANT'S AMENDMENT

- 1. The request filed on 1/21/03 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/537,858 is acceptable and a CPA has been established. An action on the CPA follows.
- 2. The numbering of claims is not accordance with 37 CFR 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 CFR 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered newly added claims 26-32 have been renumbered 24-30.

The direction to cancel claims "15-25" in the Amendment filed 1/21/03 has been interpreted to refer to all claims pending prior to entry of the amendment filed 1/21/03, i.e., claims 15-23

3. Applicant's amendment, filed 1/21/03 (Paper No. 22), is acknowledged. Claims 15-23 have been cancelled. Claims 1-14 have been cancelled previously. Claims 24-30 (as renumbered) have been added. Claims 24-30 are pending and under consideration in the instant application.

It is noted that Applicant's request to amend line 6 of page 7 (Figure 1 description) HAS NOT BEEN ENTERED as the request does not comply with 37 CFR 1.121(b).

## **Drawings**

4. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. It is noted that required drawing changes are no longer being held in abeyance by the Office. Please see the form PTO-948 previously provided as part of Paper No. 11.

# INFORMATION ON HOW TO EFFECT DRAWING CHANGES Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

#### **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

Art Unit: 1644

## Sequence Compliance

5. Sequence compliance: Applicant's provision of a corrected CRF, Sequence Listing, and Statement that the contents are identical on 1/21/03, is acknowledged. The CRF has been found acceptable and entered.

## **Priority**

6. Receipt is again acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Application 97116863.8 filed in Europe on 9/29/97; application 97122471.2 filed in Europe on 12/19/97; and application 98104216.1 filed in Europe on 3/10/98 each appear to provide adequate written support for a truncated form of RANTES lacking residues 1 and 2 (that is, "RANTES (3-68)") and a mature RANTES protein comprising 68 amino acids ("RANTES (1-68)").

In addition, each of the priority documents appears to provide adequate written support for a RANTES protein missing "up to 5" amino terminal amino acids.

As noted below, given the ambiguity in the instant claim language with respect to SEQ ID NO:2, the effective filing date of the instant claims is unclear.

Nevertheless, the interpretation of the instant claim language consistent with the disclosure does appear to have adequate written support in Applicant's priority documents.

Thus the effective filing date of the instant claims, interpreted as set forth below, is considered to be September 29, 1997.

7. This Office Action will be in response to applicant's arguments, filed 1/21/03 (Paper No. 22). The rejections of record can be found in the previous Office Action (Paper No. 16).

It is noted that New Grounds of Rejection are set forth herein.

8. Applicant's cancellation of claims 15-23 has obviated the previous objections and rejections with respect to these claims.

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Art Unit: 1644

## Claim Rejections - 35 USC § 112 second paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 24-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24-30 are indefinite in that they reference an amino acid sequence with 68 amino acids (e.g., claim 1 recites "residues 2-68 of a RANTES polypeptide according to SEQ ID NO:2"); however, SEQ ID NO:2 is only 66 amino acids in length.

For examination purposes, SEQ ID NO:2 will be interpreted as referring to a mature RANTES polypeptide as set forth in Figure 1, i.e., a polypeptide consisting of the sequence:

NH<sub>2</sub> - SPYSSDT TPCCFAYIAR PLPRAHIKEY FYTSGKCSNP AVVFVTRKNR QVCANPEKKW VREYINSLEM S -COOH

It is suggested that Applicant provide a sequence corresponding to the mature sequence of RANTES (as supported by Figure 1, where the mature polypeptide is identified as residues 1-68) as part of a newly submitted sequence listing.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

## 35 U.S.C. §§ 102 and 103

11. The following rejections under 35 U.S.C. §§ 102 and 103 are made under the assumption that the effective filing date for the instantly claimed invention is September 29, 1997.

#### Claim Rejections - 35 U.S.C. §§ 102 and 103

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1644

13. In view of the effective filing date if the instant claims, Oravecz et al (J. Exp. Med. 1997;186:1865-1872, IDS AT) no longer appears to be available as a reference under 35 USC 102(a).

14. In view of the instant claim language which excludes truncation of the N-terminus beyond those residues identified, neither Gong et al. (J. Biol. Chem. 1996;271:10521-10527, IDS AO) nor Rollins et al. (US Pat. No. 5,739,103, of record) appear to anticipate the instant claims.

15. Claims 25 and 28 (as renumbered) are rejected under 35 U.S.C. 102(b) as being anticipated by Noso et al. (J. Immunol. 1996;156:1946-1953, of record, see entire document).

Applicant's arguments, filed 1/21/03, have been fully considered but have not been found convincing.

Applicant again argues that Noso et al. do not teach that the truncated RANTES has chemokine antagonistic activity. Applicant points to the teachings of Noso et al. on page 1950, 2<sup>nd</sup> column, that the loss of two N-terminal residues, serine and proline, does not affect Eo-chemotactic activity of RANTES.

As previously noted, Noso et al. teach an amino-terminally truncated RANTES consisting of 66 amino acids and derived from dermal fibroblasts (see entire document; e.g. page 1948 2<sup>nd</sup> column, especially 5<sup>th</sup> paragraph, and Figure 3). The amino acid sequence of SEQ ID NO:2 (as defined supra) from residue 3-68 would be an inherent property of the RANTES taught by Noso et al. since Figure 3 indicates that it is the amino acids corresponding to positions 1 and 2 that are missing from the 68 amino acid from of RANTES. In addition, Noso et al. teach glycosylated species of this truncated form of RANTES (e.g. page 1948, 2<sup>nd</sup> column, especially 5<sup>th</sup> paragraph).

Applicant's comments regarding the lack of demonstrated antagonistic activity for the polypeptide of Noso et al. are acknowledged. However, the fact that RANTES lacking N-terminal amino acids Ser and Pro still was chemotactic in a particular assay does not necessarily indicate that the polypeptide lacks chemokine antagonistic activity in other assays.

Further, the structure of the polypeptide isolated by Noso et al. and the instant RANTES polypeptide consisting of residues 3-68 (as defined supra) appear to be identical. *Identical polypeptides must necessarily possess the same function*. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In the instant case Noso et al. appear to teach the identical chemical structure.

The rejection of record is therefore maintained as it applies to the instant claims.

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16. Claims 24 and 29 (as renumbered) are rejected under 35 U.S.C. 102(e) as being anticipated by Offord et al. (U.S. Pat. No. 6,168,784, see entire document).

Offord et al. teach and claim a compound comprising a RANTES polypeptide as set forth in SEQ ID NO:2 of Offord et al. (see e.g., claim 1, SEQ ID NO:2 and columns 1-2). SEQ ID NO:2 of Offord et al. is a mature RANTES polypeptide of 67 amino acids lacking the Ser found at position 1 of the mature polypeptide.

Thus SEQ ID NO:2 of Offord et al. is an isolated amino-terminally truncated RANTES polypeptide comprising residues 2-68 of a RANTES polypeptide according to SEQ ID NO:2 (as defined supra in the rejection under 35 USC 112 second paragraph), wherein the truncated RANTES lacks NH2-terminal amino acid residue 1.

Offord et al. also teach that the polypeptide has chemokine antagonistic activities (see e.g., Abstract and columns 7-8).

Offord et al. teach pharmaceutical compositions comprising the RANTES 2-68 polypeptide and a pharmaceutically acceptable carrier (see e.g., columns 8-11).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the RANTES 2-68 polypeptide taught by Offord et al.

The reference teachings thus anticipate the instant claimed invention.

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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18. Claims 24-30 (as renumbered) are rejected under 35 U.S.C. 103(a) as being unpatentable over Gong et al. (J. Biol. Chem. 1996;271:10521-10527, IDS AO).

Applicant's arguments, filed 1/21/03, have been fully considered but have not been found convincing.

Applicant argues that Gong et al. provide no reasonable expectation that the instantly claimed truncations would function as chemokine antagonists. Applicant argues that Gong et al. show that the truncation which removed fewer amino acids (i.e. a RANTES 6-68 polypeptide) produced the least displacement compared to the other truncations (e.g., RANTES 9-68). Applicant concludes that based on the teachings of Gong et al. that truncation of 5 amino acids from the amino terminus (i.e., RANTES 6-68) are less effective at displacement than the truncations of more amino acids, the ordinary artisan would not have been motivated to produce truncations involving only amino acid residue 1, 1-2, 1-3 or 1-4.

The claims are drawn to amino-terminally truncated RANTES 2-68, 3-68, 4-68 and 5-68, lacking amino-terminal amino acid residues 1, 1-2, 1-3, or 1-4 of a mature RANTES polypeptide (SEQ ID NO:2 as defined supra), respectively, and having antagonistic activity; and pharmaceutical compositions thereof.

Gong et al. have been discussed previously and teach amino terminal truncations of RANTES that have chemokine antagonistic activity (see entire document, especially Figure 1).

The Examiner has previously noted that Gong et al. also teach that the functional activity of RANTES is encoded in amino acids 1-5, since various truncations which included amino acids 1-5 resulted in forms of RANTES that lacked functional activity (e.g., page 10523, "Functional Activity of Shortened Analogs"). In addition, Gong et al. teach that truncations of RANTES involving amino acid residues 1-7, 1-8, 1-9 and 1-10 results in binding by these truncated forms of RANTES to receptors *not normally bound by full length RANTES* (e.g., page bridging paragraph of pages 10524 and 10525), causing Gong et al. to conclude that the *specificity* of RANTES lay within residues 1-6 (e.g., page 10525 last paragraph). Figure 6 shows that the truncation that removed the least of the amino terminus (i.e., RANTES 6-68) was a more specific antagonist of RANTES than the other more extensive truncations removing amino acids 1-6, 1-7, 1-8, or 1-9 of RANTES. RANTES 6-68 still displaced binding of full length RANTES, albeit less well than RANTES 7-68, RANTES 8-68, RANTES 9-68, RANTES 10-68, or full length RANTES.

Gong et al. teach screening of the various truncation in several assays which permit determination of whether a truncated form of RANTES is an antagonist, and how efficiently that particular truncation functions as an antagonist relative to other RANTES truncations (see entire document, especially the assays discussed in the Results section). Finally, Gong et al. teach that chemokine antagonists can be used to block the infiltration of cells during inflammation (e.g., see Discussion on page 10526-10527).

Gong et al. differ by not teaching an amino-terminally truncated RANTES in which only amino acid 1, amino acids 1-2, amino acids 1-3, or amino acids 1-4 are truncated from the amino terminus of RANTES (i.e., RANTES 2-68, RANTES 3-68, RANTES 4-68, or RANTES 5-68), and by not explicitly teaching a pharmaceutical composition comprising the amino-terminally truncated RANTES.

While the teachings of Gong et al. would not motivate the ordinary artisan interested in identifying *multispecific* chemokine antagonists to delete fewer than 6 amino acids; the arguments of record were not based upon the selection of multi-specific antagonists. Rather, the ordinary artisan armed with the teachings of Gong et al. would have also recognized that the design of *specific* antagonists of the chemokine RANTES would require deletions that focused upon amino acids 1-6 because these are the amino acids which Gong et al. teach control RANTES specificity, as noted supra.

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While Applicant's comments that RANTES 6-68 was less effective at displacement of full length RANTES than e.g., RANTES 9-68 are acknowledged; it is also noted that full length RANTES is the most effective specific competitor of full length RANTES (Figure 6A).

Thus the work of Gong et al. provides the ordinary artisan at the time the invention was made with a reasonable expectation that truncations of RANTES that removed fewer than 5 amino acids would still compete with full length RANTES for binding, and would do so without competing with other chemokines for binding. In addition, the teachings of Gong et al. that RANTES function required one or more amino acid residues within residues 1-5 would have motivated the ordinary artisan to screen truncations that removed 1, 1-2, 1-3, 1-4 and 1-5 amino terminal amino acids in order to produce a truncated RANTES polypeptide that did not function to induce chemotaxis or calcium flux, yet competed well for binding to the receptor compared to full length RANTES (i.e., was an antagonist of RANTES). The ordinary artisan at the time the invention was made would have been motivated to focus on shorter, rather than more extensive truncations in order to retain specificity, so that RANTES could be inhibited without inhibiting other chemokines such as MCP-1.

Therefore, the ordinary artisan at the time the invention was made would have been motivated to provide additional truncations of RANTES by focusing on residues 1-6 of the amino terminal in order to identify truncated forms of RANTES that were antagonistic for RANTES, but that did not cross inhibit interactions of other chemokines with their receptors. Given the teachings of Gong et al. that functional activity requires residues 1-5, the ordinary artisan would have been further motivated to produce and screen truncations of RANTES lacking amino terminal residues 1, 1-2, 1-3, and 1-4. In addition, given the teachings of Gong et al. that multiple amino terminal truncations of RANTES result in forms of RANTES having chemokine antagonistic activity and the teachings of assays for assessing antagonistic activity; the ordinary artisan at the time the invention was made would have had a reasonable expectation of success in producing the instantly claimed truncations, as a matter of routine optimization.

Further, the ordinary artisan would have been motivated to provide pharmaceutical compositions comprising any such antagonists in order to evaluate their relative efficacy in various disease models of inflammation, as taught by Gong et al.; and would have had a reasonable expectation of successfully utilizing these RANTES antagonistic pharmaceutical compositions in inhibiting at least some models of inflammation. Finally, glycosylated forms of the amino-terminally truncated RANTES antagonistic proteins would be produced as a consequence of many different expression systems that the ordinary artisan would utilize in order to produce sufficient quantities of the truncated RANTES.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The rejection is maintained as it applies to the instant claims.

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19. Claims 24-30 (as renumbered) are rejected under 35 U.S.C. 103(a) as being unpatentable over Rollins et al. (U.S. Pat. No. 5,739,103, of record) in view of Proudfoot et al (J. Biol. Chem. 1996: 271:2599-2603, IDS #AC).

The claims are drawn to amino-terminally truncated RANTES 2-68, 3-68, 4-68 and 5-68, lacking amino-terminal amino acid residues 1, 1-2, 1-3, or 1-4 of a mature RANTES polypeptide (SEQ ID NO:2 as defined supra), respectively, and having antagonistic activity; and pharmaceutical compositions thereof.

Rollins et al. teach and claim amino-terminally truncated chemokines having antagonistic activity, including RANTES; and methods comprising administering amino-terminally truncated chemokines including RANTES, for inhibition of chemotaxis of various cellular populations in various diseases (see entire document, especially column 1 at lines 59-62, column 3, columns 6-8, and the claims).

The amino-terminally truncated RANTES taught by Rollins et al. include truncations that are "about 1 to about 10 or about 2 to about 7" of the endogenous chemokine sequence (see e.g., column 3, especially lines 18-34, and claims).

Rollins et al. teach assays for identifying truncations of chemokines that are antagonistic by exemplifying identification of MCP-1 antagonists (see e.g., columns 9-11).

In addition, Rollins et al. teach recombinant production of amino-terminally truncated chemokines in eukaryotic cells, which would inherently result in a glycosylated protein (e.g., column 8, especially lines 11-20). Finally, Rollins et al. teach the formulation of the amino-terminally truncated RANTES in a pharmaceutically acceptable carrier for administration to a patient for treatment of a RANTES-mediated disease (e.g. columns 6-7).

Rollins et al. do not explicitly teach truncations of RANTES that are RANTES 2-68, RANTES 3-68, RANTES 4-68 or RANTES 5-68.

However, these species are encompassed by the small genus of truncations which are explicitly taught and claimed by Rollins et al. (i.e., truncations involving about 1 to about 10 amino terminal amino acids).

Further Proudfoot et al. teach recombinant expression of RANTES, and also teach that the integrity of the amino terminus of RANTES is crucial to receptor binding and cellular activation (see entire document, especially Experimental Procedures on pages 2599-2560 and the Discussion on page 2602).

Like Rollins et al., Proudfoot et al. teach that antagonists of RANTES function are made by modifying the amino terminus of RANTES (see entire document, e.g., Discussion on page 2602). Proudfoot et al. also provide detailed guidance regarding the uses of antagonists of RANTES in inhibition of chronic inflammatory diseases (see e.g., Abstract and Introduction on page 2599).

Thus Rollins et al. provide a general teaching with respect to the production of chemokine antagonists via truncation of amino acids at the amino terminus of any of several chemokines, and Proudfoot et al. establish that modification of the amino terminus of RANTES results in antagonistic properties.

Rollins et al. provide clear guidance to delete amino acids from position 1 to position 10 of the amino terminus. The ordinary artisan would have produced the instantly recited truncations as part of the routine optimization and screening of the small genus of truncations taught by Rollins et al.

Both Rollins et al. and Proudfoot et al. teach production of RANTES antagonists by modifying the amino terminus. Both Rollins et al. and Proudfoot et al. teach that RANTES antagonists can be used to inhibit chemotaxis of cells responsive to unmodified RANTES and thereby inhibit various inflammatory disorders.

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Rollins et al. teach a small genus of amino terminal truncations of chemokines including RANTES, but does not reduce to practice or explicitly list the members of this genus.

The ordinary artisan at the time the invention was made would have been motivated in view of the teachings of Rollins et al. alone, but particularly when combined with the teachings of Proudfoot et al., to make the members of the small genus of amino terminal truncations of RANTES et al. taught by Rollins et al. The ordinary artisan at the time the invention was made would have been motivated to make the instantly recited truncations and formulate them in pharmaceutically acceptable carriers in order to compare the relative potency of each member of the small genus taught by Rollins et al. as antagonists in models of inflammation; and thereby identify the most potent antagonist.

Given the teachings by both Rollins et al. and Proudfoot et al. that modifications of the amino terminus of RANTES resulted in an antagonist, the ordinary artisan at the time the invention was made would have had a reasonable expectation that most, if not all, members of the genus taught by Rollins et al. would function as antagonists. Further, given the guidance provided by both Rollins et al. and Proudfoot et al. as to how to make and screen for RANTES antagonists in multiple expression systems; the ordinary artisan at the time the invention was made would have had a reasonable expectation of making the instantly claimed truncations in either glycosylated or unglycosylated form. Thus the ordinary artisan at the time the invention was made would have found it obvious to make the RANTES 2-68, RANTES 3-68, RANTES 4-68 or RANTES 5-68 truncations recited in the instant claims.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### Conclusion

#### 20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D. Patent Examiner Technology Center 1600 March 27, 2003

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TOCH CONTON 1600

## Application/Control No. Applicant(s)/Patent Under Reexamination 09/537,858 PROOST ET AL. Notice of References Cited Art Unit Examiner Page 1 of 1 Jessica H. Roark 1644 **U.S. PATENT DOCUMENTS** Document Number Date Classification Name Country Code-Number-Kind Code MM-YYYY Α US-6,168,784 01-2001 Offord et al. В US-С US-US-D Ε US-F US-US-G US-Н US-Į J US-US-K US-L US-М FOREIGN PATENT DOCUMENTS Document Number Country Code-Number-Kind Code Date Classification Name Country MM-YYYY Ν 0 Р Q R s T **NON-PATENT DOCUMENTS** Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) U ٧ W

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



FEB 20 2003

Commissioner for Patents Washington, DC 20231 www.uspto.gov

Dear Patent Business Customer:

The United States Patent and Trademark Office ("Office") is now permitting and encouraging applicants to voluntarily submit amendments in a revised format as set forth in AMENDMENTS IN A REVISED FORMAT NOW PERMITTED, \_\_\_\_\_ Off. Gaz. Pat. Office \_\_\_ (February 25, 2003), currently available on the USPTO web site at <a href="http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm">http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm</a>. The revised format permits amendments to the specification and claims to be made in a single marked-up version; the requirement for a clean version is eliminated. Attached, you will find a flyer with information and instructions regarding the procedures to be used to comply with the revised format. The flyers are being inserted with out-going Office actions mailed during the period of February 20, 2003 - March 31, 2003.

The revised amendment format is essentially the same as the amendment format for the specification, claims, and drawings that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. This proposed revision and others necessary to facilitate a gradual transition to the use of an Electronic File Wrapper (EFW) will be set forth in a Notice of Proposed Rule making (NPR), expected to be published by March 2003. After consideration of public comments, the Office anticipates adopting a revision to § 1.121, following publication of a Notice of Final Rule making (NFR), expected by June 2003, at which point compliance with revised § 1.121 will be mandatory.

The Office will continue to accept your amendment submissions in the revised format during the voluntary period, which will extend up to the effective date of final revisions to § 1.121. The Office also encourages your feedback on the proposed revised amendment format and other changes set forth in the NPR, expected to be published by March 2003.

For assistance: Any questions regarding the submission of amendments pursuant to the revised practice should be directed to Office of Patent Legal Administration (OPLA), Legal Advisors Elizabeth Dougherty (Elizabeth.Dougherty@uspto.gov), Gena Jones (Eugenia.Jones@uspto.gov) or Joe Narcavage (Joseph.Narcavage@uspto.gov). Alternately, you may send e-mail to "Patent Practice", the OPLA e-mail address that has been established for receiving queries and questions about patent practice and procedures or telephone OPLA at (703) 305-1616.

Nicholas P. Godici

Commissioner for Patents

Attachment: Flyer entitled: Revised Notice\* AMENDMENTS MAY NOW BE SUBMITTED IN REVISED FORMAT

U.S. DEPARTMENT OF COMMERCE-Patent and Trademark Office

Application No. 9/537,858

OCT 0 2 2003

## NOTICE OF DRAFTPERSON'S PATENT DRAWING REVIEW

trawing filled (taken date) 3-26 · OO are:

TRADEM not objected to by the Draftperson under 37 CFR 1.84 or 1.152.

B. \_\_\_\_\_\_\_objected to by the Draftperson under 37 CFR 1.84 or 1.152 as indicated below. The Examiner will require submission of new, corrected drawings whe necessary. Corrected drawings must be submitted according to the instructions on the back of this notice.

DRAWNOS. 37 CFR 1.84(a): Acceptable categories of drawings:   Black ink. Color.   Color drawing are not acceptable until petition is granted.     Fig. 6)	<u></u>
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6. VIEWS. CFR 1.84(h) REMINDER: Specification may require revision to correspond to drawing changes.  — Views connected by projection lines or lead lines. Fig.(s) — Brackets needed to show figure as one entity. Fig.(s) — Views not labeled separately or properly. Fig.(s) — Enlarged view not labeled separately or properly. Fig.(s) — Enlarged view not labeled separately or properly. Fig.(s) — Solid black shading not used for color contrast. Fig.(s) — Solid black shading not used for color contrast. Fig.(s) — Solid black shading not used for color contrast. Fig.(s) — Solid black shading not used for color contrast.	rection as the view. 37 CFR 1.84(p)(3) Fig.(s)
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Views connected by projection lines or lead lines.  Fig.(s)	
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Partial views. 37 CFR 1.84(h)(2)  Brackets needed to show figure as one entity.  Fig.(s)  Views not labeled separately or properly.  Fig.(s)  Enlarged view not labeled separately or properly.  Fig.(s)  Fig.(s)  Diagram of the bed separately or properly.  Fig.(s)  Enlarged view not labeled separately or properly.  Fig.(s)  Fig.(s)  Sheets not numbered consecutively, and in Ababic numerals beginning with number 1. Fig.(s)  Views not numbered consecutively, and in Abrabic numerals, beginning with number 1. Fig.(s)  Corrections. 37 CFR 1.84(w)  Corrections not made from PTO-948 dated  17. DESIGN DRAWINGS. 37 CFR 1.152  Surface shading shown not appropriate. Fig.(s)  Solid black shading not used for color contrast.  Fig.(s)  Solid black shading not used for color contrast.	
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